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Datasheet for the decision
of 9 March 2023

Case Number:	T 1039/20 - 3.2.02
Application Number:	10765238.0
Publication Number:	2419009
IPC:	A61B5/00
Language of the proceedings:	EN

Title of invention:
SYSTEM AND METHOD FOR CONFIGURING A RULE SET FOR MEDICAL EVENT
MANAGEMENT AND RESPONSES

Applicant:
ICU Medical, Inc.

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:

Decisions cited:

Catchword:

Case Number: **T 1039/20 - 3.2.02**

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 9 March 2023

Appellant:	ICU Medical, Inc.
(Applicant)	951 Calle Amanecer
	San Clemente, CA 92673 (US)
Representative:	Invent Horizon IP
	Nordenskiöldsgatan 11A
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Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 6 November 2019 refusing European patent application No. 10765238.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	M. Alvazzi Delfrate
Members:	A. Martinez Möller
	Y. Podbielski

Summary of Facts and Submissions

I.   The appeal is against the decision of the examining
        division refusing European patent application No.
        10765238.0. The examining division found that the main
        request complied with the requirements of Article
        123(2) EPC but that it did not involve an inventive
        step within the meaning of Article 56 EPC.

II.   The appellant requested that the decision under appeal
        be set aside and that a patent be granted on the basis
        of the main request or, as an auxiliary measure, that a
        patent be granted on the basis of one of auxiliary
        requests 4 or 5, all filed with the letter dated
        12 March 2020.

III.   Claim 1 of the main request reads as follows:

        "A method for generating and storing a medical system
        algorithm for use in connection with an automated
        medical device (130) within a medical system, the steps
        of the method comprising:
            providing a context free grammar to define the
        medical system algorithm, the grammar comprising non-
        terminal parameter symbols and terminal parameter
        symbols that are configured to be satisfied by a
        plurality of non-terminal medical system parameters and
        terminal medical system parameters, respectively, the
        grammar further comprising non-terminal condition
        symbols and terminal condition symbols that are
        configured to be satisfied by a plurality of non-
        terminal medical system conditions and terminal medical
        system conditions, respectively, the grammar further

comprising a response symbol that is configured to be satisfied by a plurality of medical system responses;

receiving, by a rule set configuration processor (140), a first parameter selection comprising at least one of the non-terminal parameters or at least one of the terminal parameters, defined by the grammar;

receiving, by the rule set configuration processor (140), a respective first medical system condition selection corresponding to the at least one of the non-terminal parameter symbol or terminal parameter symbol for the selected first parameter selection defined by the grammar;

receiving, by the rule set configuration processor (140), a medical system response selection;

generating the medical system algorithm from the first parameter selection, the first medical system condition selection, and the medical system response selection; and

storing in a computer readable memory the generated medical system algorithm for later use by said automated medical device (130) wherein the generated medical system algorithm can be independently selectable without changing to a different protocol or personality of the automated medical device (130);

wherein each of the first parameter selection, the first medical system condition selection, and the medical system response selection may be inputted by a user via an interface (500),

receiving, by the rule set configuration processor (140), a second parameter selection comprising at least of [*sic*] one of the non-terminal parameter symbols or at least one of the terminal parameter symbols defined by the grammar; and

receiving, by the rule set configuration processor (140), a respective second medical system condition selection corresponding to the at least one of the non-

terminal parameter symbol or terminal parameter symbol
for the selected second parameter selection defined by
the grammar, wherein each of the second parameter
selection and the second medical system condition
selection is inputted by said user via said interface
(500),

wherein the first medical system parameter
selection is a first alarm selection and wherein the
second medical system parameter selection is a second
alarm selection, different than the first alarm
selection,

wherein said medical system response selection
specifies switching the medical system algorithm to a
second medical system algorithm generated from the
second parameter selection and the second medical
system condition selection."

IV.   The following documents are relevant to this decision.

D1   US 2005/020886 A1
D2   US 2006/047538 A1
D3   "The syntax and semantics of the PROforma
guideline modeling language", JOURNAL OF THE AMERICAN
MEDICAL INFORMATICS ASSOCIATION, vol. 10, no. 5,
September 2003 (2003-09), pages 433-443, ISSN:
1067-5027, DOI: 10.1197/JAMIA.M1264
D4   VAN DER MAAS A A F ET AL: "Requirements for
Medical Modeling Languages", JOURNAL OF THE AMERICAN
MEDICAL INFORMATICS ASSOCIATION, vol. 8, no. 2,
1 March 2001 (2001-03-01), pages 146-162

V.   The appellant's arguments which are relevant to the
present decision can be summarised as follows.

Inventive step when starting from D1

The subject-matter of claim 1 was inventive when
starting from D1.

D1 did not disclose a medical system response selection
specifying switching the medical system algorithm to a
second medical system algorithm generated from a second
parameter selection and a second medical system
condition selection, where first medical system
parameter selection was a first alarm selection and
wherein the second medical system parameter selection
was a second alarm selection, different than the first
alarm selection.

A technical effect from the distinguishing feature was
a more efficient handling of alarms in a medical
system. The objective technical problem was how to
improve alarm handling efficiency in such system.
Neither D1 nor any of the other documents on file
taught the solution of claim 1.

Reasons for the Decision

1.   **The invention**

Patients can be monitored using biometric sensors
including an EKG system, respiratory monitors and blood
gas monitors. Medical equipment such as a medication
delivery pump can also be monitored, for example to
identify when an interruption of the regular operation
has happened.

Systems to monitor patients and equipment provide
outputs which can be used by caregivers to make various
patient care decisions. They may also trigger an alarm

if a deviation is detected, for example a "low blood pressure" alarm.

Conventional monitoring systems have some drawbacks, including false positive alarms and the lack of ability to require a response only when multiple monitored parameters have changed. For example, a momentary deviation such as a brief disconnection from a biometric sensor may lead to an alarm being triggered also when no action from the caregiver is needed. A false alarm may cause an improper reaction from the caregiver. Frequent false alarms may also desensitize caregivers.

The invention addresses these drawbacks by using two medical system algorithms (i.e. two rule sets). Each algorithm is generated with a respective medical system parameter selection and medical system condition selection. The medical system parameter selection of each of the two algorithms is an alarm selection, with the two alarm selections being different.

The (first) medical system algorithm is generated with a medical system response selection which specifies switching the algorithm to the second medical system algorithm.

An example of a rule set comprising parameters/alarms, conditions and responses is shown in Figure 4 of the patent application reproduced below.
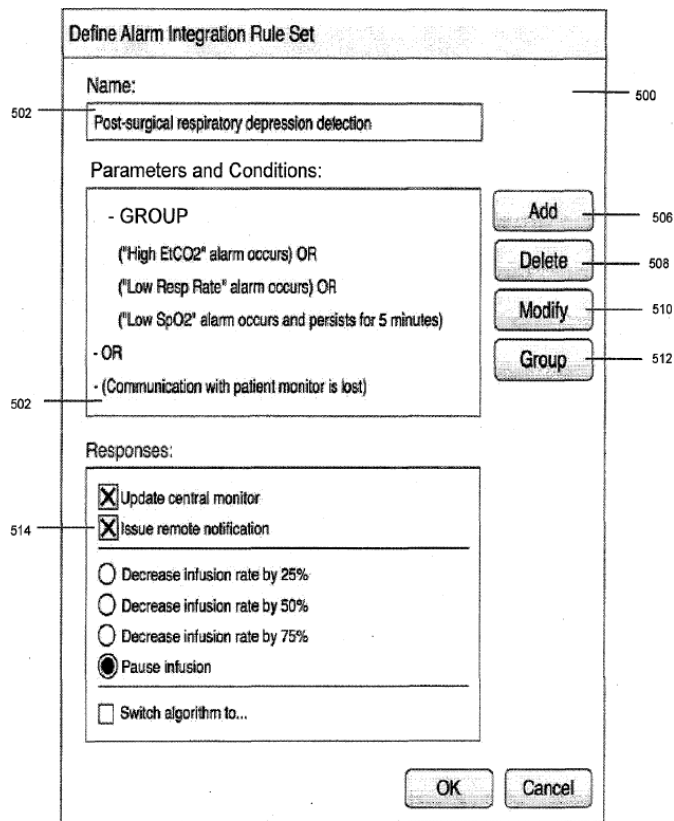
Figure 4

2.   Main request – inventive step

2.1   D1 deals with patient monitoring using rule-based
        algorithms and defines a valid starting point for the
        invention of claim 1. D1 teaches that one or more rule-
        based algorithms can be applied to physiologic
        variables in order to establish one or more diagnostic
        interpretations.

2.2   The appealed decision identified the feature "providing
        a context free grammar ..." as defining the sole
        distinguishing feature of the claimed invention over
        D1. This feature was found to be a so-called non-
        technical feature which did not result in a technical

effect serving a technical purpose. This assessment was not disputed by the appellant and the Board sees no need to address it further. However, as explained hereafter, further features distinguish the claimed method from D1.

2.3   The rule-based algorithm(s) disclosed in D1 can be regarded as the "medical system algorithm" of claim 1.

2.3.1   D1 discloses that the selection of which rule set(s) / rule-based algorithm(s) to apply can previously be done by the logic 22 (see paragraphs [0021], [0028] and claim 13 of D1). It is not fully clear from the feature analysis in the appealed decision whether the examining division regarded the rule-based algorithm(s) or their pre-selection as anticipating the "medical system algorithm" of claim 1. The Board regards the latter possibility as less appropriate for two reasons.

2.3.2   Firstly, according to claim 1, both the medical system algorithm and the second medical system algorithm are defined using symbols from a common context free grammar. However, D1 comprises no indication that the selection of which rule-based algorithm(s) to use would be represented as an algorithm using symbols from the same grammar as the rule-based algorithms themselves.

2.3.3   Secondly and more importantly, the passage of D1 relating to the physiologic variables showing a development comparable to an alarm (i.e. "drop in oxygen in a patient's blood" in paragraph [0019]) is within the context of applying the logic rules / algorithms to derive a diagnostic interpretation. D1 does not disclose that any such developments would be identified or that anything equivalent to an alarm

would play any role when selecting which rule set(s) /
algorithm(s) to apply.

2.4   The rule-based algorithm(s) of D1 receive physiologic
        variables 17 as input and generate a response such as
        an alarm or a diagnostic interpretation (see paragraphs
        [0018]-[0019] and [0030] of D1).

2.4.1   As explained in the appealed decision, the plurality of
        physiologic variables 17 of D1 can be regarded as
        anticipating the claimed "first parameter selection" ,
        while the "first medical system condition selection" is
        anticipated by comparisons of the type less-than or
        equal-to implicitly used to establish a drop in oxygen
        or a drop in CO2 level, mentioned in paragraph [0019]
        of D1.

2.4.2   The claimed "medical system response selection" is
        anticipated by the alarm, diagnostic interpretation,
        etc. that can be the response of the rule-based
        algorithm according to paragraph [0030] of D1.

2.5   However, D1 does not disclose that the "first [medical
        system] parameter selection" is a "first alarm
        selection".

2.5.1   In respect of this feature the appealed decision refers
        to the alarm of paragraph [0030] or to the physiologic
        variables 17. Neither of the approaches is convincing:

2.5.2   The alarm is disclosed in D1 as a possible response of
        the rule-based algorithm, not as a possible parameter.

2.5.3   As regards the physiologic variables 17, the decision
        indicates that they could show a development such as a
        drop in oxygen in a patient's blood which is equivalent

to an alarm. However, as also argued in the appealed decision, this is done in D1 in the context of what would be the "medical system condition selection", i.e. the algorithm's parameters in D1 are the physiologic variables and any such development equivalent to an alarm could only be implied by the algorithm's conditions/comparisons. It follows that the plurality of physiologic variables 17 may anticipate a "first parameter selection" within the meaning of claim 1, but this first parameter selection is not a "first alarm selection".

2.6   Moreover, the last feature of claim 1 ("wherein said medical system response selection specifies switching the medical system algorithm to a second medical system algorithm ...") is not disclosed in D1 either.

2.6.1   The examining division construed said feature as encompassing the possibility of merely prompting a user to perform the switching to a second algorithm (see point 2.2.2 of the appealed decision). The Board construes the feature differently. The feature relates to the response/action provided by the generated medical system algorithm of claim 1. Switching to another algorithm is not the same response as merely prompting the user to switch to another algorithm, nor does the former encompass the latter.

2.6.2   A different interpretation is not supported by the description either. The most relevant passage seems to be the second sentence of paragraph [0060], which reads as follows:

           This change [to the second rule set] could be automatic, in the case where the response specifies that the rule set be switched, or it could merely

be suggested in the case where the rule set is
configured to suggest to the caregiver that he or
she switch rule sets.

The algorithm's response as defined in claim 1 is
"switching" to a second medical system algorithm,
corresponding to the first alternative in the sentence
above. This sentence can thus not support that
"switching" in claim 1 encompasses the second
alternative of providing a suggestion.

2.6.3   The possible responses of the rule-based algorithm(s)
of D1 are recited in paragraph [0030] and do not
include switching to a different algorithm. Hence, the
last feature of claim 1 represents a further difference
in view of D1.

2.7   It follows that the last two features of claim 1 define
additional distinguishing features over D1.

2.8   These two features allow the generated algorithm to
switch to a different algorithm if the conditions on
the first parameter selection which is a first alarm
selection are met. Thereby, successive algorithms /
rule sets may be linked. This may be used for example
with two algorithms having a different sensitivity to
externally generated alarms (see the penultimate
sentence of paragraph [0060] of the patent
application).

2.9   The Board agrees with the appellant that the technical
effect can be seen as achieving a more efficient
handling of parameters/alarms in a medical system. The
objective technical problem may thus be regarded as how
to provide an algorithm which improves parameter
handling efficiency.

2.10   The person skilled in the art starting from D1 finds no
         hint in the available prior art towards the solution of
         claim 1.

2.10.1   D2 deals with monitoring the therapy delivered to a
         patient. Alarms may be issued if the monitored
         information does not fall within an acceptable range
         according to certain rules (see paragraphs [0020] and
         [0026] of D2). D2 acknowledges that not all alarms are
         equally important and addresses this issue by applying
         further rules to an alarm to determine whether or not
         the alarm should be communicated to care givers (see
         paragraphs [0111]-[0112]).

2.10.2   Even assuming that the person skilled in the art
         starting from D1 and trying to solve this problem would
         consider the teaching of D2, he or she would not arrive
         at the claimed solution. Following the teaching of D2
         he/she would use the alarm which may be provided as
         response of a (first) rule-based algorithm (see
         paragraph [0030], 3rd sentence, of D1) as a parameter
         for a second rule-based algorithm and would also
         specify switching to this second rule-based algorithm
         as part of the response of the first rule-based
         algorithm. This would lead to a first rule-based
         algorithm which has physiologic variables as parameters
         and a second rule-based algorithm which has an alarm
         selection as parameter. Hence, even with these
         modifications, the "first parameter selection" would
         not be a "first alarm selection", so that the
         penultimate feature of claim 1 would not be
         anticipated. It follows that starting from D1 and in
         view of D2 the person skilled in the art would not
         arrive at a method anticipating the subject-matter of
         claim 1.

2.10.3 D3 and D4 deal with modeling languages for clinical
        applications without addressing the problem indicated
        above.

2.11   It follows that the subject-matter of claim 1 involves
        an inventive step.

Order

For these reasons it is decided that:

1.   The decision under appeal is set aside.

2.   The case is remitted to the examining division with the
        order to grant a patent on the basis of the main
        request filed with the letter dated 12 March 2020 and a
        description to be adapted thereto.

The Registrar: The Chair:

A. Chavinier-Tomsic   M. Alvazzi Delfrate

Decision electronically authenticated